2003-04

Immunizers' Question & Answer Guide to Medicare Coverage

of

Influenza and Pneumococcal Vaccinations

Steps to Promoting Wellness: Adult Immunizations

The issues involved in Medicare billing and administration can be complex and may vary state to state. For this reason, we recommend that you contact your local Medicare intermediary (Part A), carrier (Part B), or CMS Regional Office for more detailed information.

Centers for Medicare & Medicaid Services
Center for Beneficiary Choices/QMHAG
Mail Stop: S3-02-01
7500 Security Boulevard
Baltimore, MD 21144

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A. INTRODUCTION

Purpose

This document addresses immunizers' commonly asked questions about the administration of influenza and pneumococcal vaccines to Medicare patients. It also includes questions and answers that are particularly relevant to the 2003-04 influenza immunization season.

The following information will be useful for immunizers, however, the issues involved in Medicare billing and administration can be complex and may vary from state to state. For additional, detailed information, contact your local Medicare intermediary (Part A), carrier (Part B), or the Centers for Medicare & Medicaid Services (CMS).

The following sections provide a summary of the current recommendations of the Advisory Committee on Immunization Practices (ACIP) as they relate to adult immunization; Medicare coverage and payment policy; requirements for mass immunizers and centralized billing; and a brief discussion of managed care. In addition, a list of definitions is included.

Background of Medicare pneumococcal and influenza vaccination benefits

Pneumococcal disease, *Streptococcus pneumoniae*, and influenza together are the fifth leading cause of death in the United States among persons aged 65 years or older. Epidemics of influenza are responsible for an average of approximately 20,000 deaths per year in the U.S., of which more than 90 percent occur among those aged 65 or older. Pneumococcal infection causes an estimated 125,000 hospitalizations for pneumonia annually in the U.S. Most deaths due to pneumococcal disease occur in persons aged 65 and older.

The U.S. Congress established the Medicare program in 1965. Coverage for preventive services has been added since 1980, and use of preventive services has increased over time. These preventive services include three types of immunizations: pneumococcal, hepatitis B, and influenza. The Medicare program has covered pneumococcal polysaccharide vaccine (PPV) and its administration since July 1, 1981. Coverage for the influenza virus vaccine and its administration was added May 1, 1993.

U.S. immunization rates have increased but have far to go. In 1999, 54.1 percent of persons aged 65 years and older had ever received a pneumococcal vaccine. In 1999, influenza immunization rates for this group were 66.9 percent – double the 1989 immunization rate of 33 percent. The Leading Health Indicators established by Healthy People 2010 target both vaccination rates to reach 90 percent for persons age >65 years.

ACIP Guidelines

Clinicians should refer to published guidelines for current recommendations related to immunization. ACIP is the only entity within the federal government that makes written recommendations for routine administration of vaccines to pediatric and adult populations. The Infectious Diseases Society of America (IDSA) and the American Thoracic Society (ATS) also discuss vaccination in their guidelines. At the time of this writing, the most recent ACIP Recommendations for the Prevention of Pneumococcal Disease were published in the April 4, 1997 *MMWR*. The guidelines for the Prevention and Control of Influenza were published April 25, 2003, and an erratum was issued June 6, 2003. Internet website addresses for these documents are provided on page 7.

State laws governing who may administer PPV and influenza vaccines and how the vaccines may be transported vary widely. In addition to staying abreast of current guidelines, CMS urges providers and suppliers to stay current with state immunization regulations.

Summary of ACIP Guidelines

Pneumococcal

ACIP recommends that all persons receive a dose of pneumococcal vaccine when or after they reach age 65. Persons who receive a dose before age 65 are recommended to receive another dose after they turn age 65, once 5 years have elapsed since their prior dose. The pneumococcal vaccine is generally a once-in-a-lifetime after age 65 vaccination that can be given at any time during the year. All persons who have unknown vaccination status should receive one dose of vaccine. Pneumococcal vaccine may be administered at the same time as influenza vaccine (by separate injection in the other arm).

According to ACIP, pneumococcal vaccine is recommended for the following groups of persons who are at increased risk from invasive pneumococcal disease or its complications:

- Children less than 2 years of age (pneumococcal conjugate vaccine) and adults aged 65 or more (polysaccharide vaccine);
- Adults who have chronic cardiovascular diseases (e.g., congestive heart failure or cardiomyopathy), chronic pulmonary diseases (e.g., chronic obstructive pulmonary disease [COPD] or emphysema), or chronic liver diseases (e.g., cirrhosis);
- Adults with diabetes mellitus. Diabetes is associated with cardiovascular or renal dysfunction, both of which increase the risk for severe pneumococcal illness;
- Persons who have liver disease as a result of alcohol abuse;
- Persons with functional or anatomic asplenia (e.g., sickle cell disease or splenectomy). This group is at very high risk for pneumococcal infection,

because this condition leads to reduced clearance of encapsulated bacteria from the bloodstream.

- Persons with cerebrospinal fluid (CSF) leakage resulting from congenital lesions, skull fractures, or neurosurgical procedures. These persons are at risk for recurrent pneumococcal meningitis;
- Persons who have decreased responsiveness to polysaccharide antigens or an increased rate of decline in serum antibody concentrations as a result of
  a) immunosuppressive conditions (e.g., congenital immunodeficiency, human immunodeficiency virus [HIV] infection, leukemia, lymphoma, multiple myeloma, Hodgkins disease, or generalized malignancy). *S. pneumoniae* is the most commonly identified bacterial pathogen that causes pneumonia in HIV-infected persons;
  b) organ or bone marrow transplantation;
  c) chemotherapy with alkylating agents, antimetabolites, or systemic corticosteroids;
  d) systemic corticosteriods; or
  e) chronic renal failure or nephrotic syndrome.

About 78% of adults who have invasive pneumococcal infection have at least one of the previously mentioned underlying medical conditions, including age greater than or equal to 65 years.

Because asthma has not been associated with an increased risk for pneumococcal disease, persons with asthma do not need pneumococcal vaccine unless they have asthma as part of chronic bronchitis or emphysema or they use long-term systemic corticosteriods.

Influenza

The 2003 ACIP recommendations made these notable updates and changes:

The optimal time to receive influenza vaccine continues to be October and November. However, because of vaccine distribution delays during 2000-2002 season, ACIP now recommends that vaccination efforts in October focus on:

- Persons aged $\geq$50 years
- Those aged 6-23 months
- Persons aged 2-49 years with certain medical conditions that place them at increased risk for influenza-related complications
- Children aged <9 years receiving influenza vaccine for the first time
- Health-care workers
- Household contacts of persons at high risk

Because young, otherwise healthy children are at increased risk for influenza-related hospitalization, influenza vaccination of healthy children aged 6-23 months continues to be encouraged when feasible. Vaccination of children aged ≥6 months who have certain medical conditions continues to be strongly recommended

Mass immunization clinics held prior to November should focus on the high-risk groups and their household contacts. Healthy persons aged 9-64 years (and those 2-8 years who are not receiving vaccine for the first time), who are not household contacts of high-risk persons, and who do not fit into any of the groups listed above should wait until November to seek vaccination. Vaccination should continue through December and later, as long as vaccine supplies are available.

According to ACIP, high priority target groups to receive influenza vaccination are persons who are at increased risk for complications from influenza:

- Persons aged ≥65 years;
- Residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions;
- Adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including asthma;
- Adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency [HIV] virus);
- Children and adolescents (aged 6 months-18 years) who are receiving long-term aspirin therapy and, therefore, might be at risk for developing Reye syndrome after influenza infection;
- Women who will be in the second or third trimester of pregnancy during the influenza season; and
- Children 6-23 months.

ACIP also recommends that persons aged 50-64 years receive this vaccine, because this entire age group has an increased prevalence of high-risk conditions.

Persons who can transmit influenza to those at high risk also need to be vaccinated, according to ACIP. Vaccination of health-care workers and others in close contact with persons at high risk, including household members is recommended:

- Physicians, nurses, and other personnel in both hospital and outpatient-care settings (including medical emergency response workers);
- Employees of nursing homes and chronic-care facilities who have contact with patients or residents;

- Employees of assisted living and other residences for persons in groups at high risk;
- Persons who provide home care to persons in groups at high risk; and
- Household contacts (including children) of persons in groups at high risk, including household contacts and out-of-home caregivers of children 0-23 months.

Contacts/Resources for More Information

ACIP Guidelines

- ACIP List of Recommendations, http://www.cdc.gov/nip/publications/ACIP-list.htm
- ACIP Recommendations for the Prevention of Pneumococcal Disease, MMWR, April 4, 1997, www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm (html), http://www.cdc.gov/mmwr/PDF/rr/rr4608.pdf (pdf)
- ACIP Recommendations for the Prevention and Control of Influenza, MMWR, April 25, 2003, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5208a1.htm (html), http://www.cdc.gov/mmwr/PDF/rr/rr5103.pdf (pdf)
- MMWR Erratum, June 6, 2003, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5222a5.htm

CDC National Immunization Program

- http://www.cdc.gov/nip

Medicare Carrier Manual (MCM)

- Billing for PPV, Hepatitis B and Flu Virus Vaccines, http://cms.hhs.gov/manuals/11_hha/hh460.asp#_1_473
- Centralized billing, http://cms.hhs.gov/manuals/14_car/3b2049.asp - _2049_0
- Coverage & Limitations: Drugs and biologicals, http://cms.hhs.gov/manuals/14_car/3b2049.asp - _2049_0

Forms

- CMS Paper Forms and Instructions, http://www.hcfa.gov/medicare/edi/edi5.htm

Immunization Practices FAQ

- Refer to CMS site for best practices at: http://www.medqic.com/

B. COVERAGE POLICY

Coverage Criteria

B1. What are Medicare's coverage criteria for flu vaccinations?

Effective for services performed on or after May 1, 1993, Medicare will pay for flu virus vaccines and their administration. Generally, only one flu virus vaccination is medically necessary per year. Medicare beneficiaries may receive the vaccine once each flu season without a physician's order and without the supervision of a physician. However, state laws regarding who can administer vaccines still apply. The Medicare Part B deductible and coinsurance do not apply. Additional vaccination may be covered if medically necessary.

B2. What are Medicare's coverage criteria for Pneumococcal Polysaccharide Vaccine (PPV) vaccinations?

Effective for services performed on or after July 1, 1981, Medicare began paying for PPV and its administration. Typically, this vaccine is administered once in a lifetime except for persons at highest risk.

Effective for claims with dates of service on or after July 1, 2000, Medicare no longer requires the PPV to be ordered by a doctor of medicine or osteopathy. However, state laws regarding who can administer vaccines still apply. Therefore, the beneficiary may receive the vaccine upon request without physician's supervision. However, state laws regarding who can administer vaccines still apply.

Medicare will only cover an initial vaccine administered to persons at high risk of pneumococcal disease. Considered at high risk are persons 65 years of age or older and immunocompetent adults who are at increased risk of pneumococcal disease or its complications because of chronic illness.

Provided that at least five years have passed since receipt of a previous dose of PPV vaccine, revaccination may be administered only to persons at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels. This group includes persons with functional or anatomic asplenia (e.g., sickle cell disease, splenectomy), HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression such as organ or bone marrow transplantation, and those receiving immunosuppressive chemotherapy. Routine revaccination of people age 65 or older is not appropriate, unless determined medically necessary by a physician, unless initial vaccination was given before age 65, and 5 years has passed.

B3. Could you provide clarification regarding the "when in doubt rule" concerning re-vaccination of Medicare patients with the pneumonia vaccine when they don't remember if they have been vaccinated?

Persons aged 65 years or more should be administered a second dose of vaccine if they received the vaccine more than 5 years previously and were less than 65 years at the time of primary vaccination. Persons aged 65 years or older with unknown vaccination status should be administered one dose of vaccine.

B4. Will Medicare pay for vaccination if an individual cannot produce documentation or is not sure whether they have received a PPV shot?

Yes. Those administering the vaccine should not require the patient to present an immunization record prior to administering PPV, nor should they feel compelled to review the patient's complete medical record if it is not available. Instead, provided that the patient is competent, it is acceptable to rely on the patient's verbal history to determine prior vaccination status. If the patient is uncertain about their vaccination history in the past five years, the vaccine should be given. However, if the patient is certain he/she was vaccinated in the last five years, the vaccine should not be given. If the patient is certain that the vaccine was given and that more than five years have passed since receipt of the previous dose, revaccination is not appropriate unless the patient is at highest risk.

B5. Will Medicare pay for the revaccination if an individual, not at highest risk, is revaccinated for PPV?

Yes, if a beneficiary who is not at highest risk is revaccinated because of uncertainty about his or her vaccination status, Medicare will cover the revaccination.

Eligibility

B6. Is a person with only Part A coverage entitled to receive the flu and PPV vaccinations and have them covered under Part B?

No. The flu and PPV vaccines and their administration are a Part B covered service only.

B7. Will Medicare pay a home health agency (HHA) for a nurse's visit when he or she goes into a patient's home to furnish the flu or PPV vaccine?

It depends on the circumstances. If the sole purpose for a home health agency (HHA) visit is to administer a vaccine (flu, PPV, or hepatitis B), Medicare will not pay for a skilled nursing visit by an HHA nurse under the HHA benefit. However, the vaccine and its administration are covered under the vaccine benefit. The administration should

include charges only for the supplies being used and the cost of the injection. HHA's are not permitted to charge for travel time or other expenses (e.g., gasoline).

Medicare Requirement for Consent

B8. Is a physician order (written or verbal), plan of care, or any other type of physician involvement required for Medicare coverage of the flu and PPV vaccinations?

No. For Medicare coverage purposes, it is no longer required that either of the vaccines be ordered by a doctor of medicine or osteopathy though individual state law may require a physician order or other physician involvement. Therefore, the beneficiary may receive the vaccines upon request without a physician or osteopath's order.

Who Can Bill

B9. Which individuals and what entities may bill Medicare for the flu and PPV vaccines and their administration?

Any individual or entity meeting state licensure requirements may qualify to have payment made for furnishing and administering the flu and PPV vaccines to Medicare beneficiaries enrolled under Part B.

Who to Bill

B10. What types of providers and suppliers may bill the intermediary for the flu and PPV vaccinations?

The following providers of services may bill intermediaries for this benefit:

- Hospitals;
- Skilled Nursing Facilities (SNFs);
- Religious Non-Medical Health Care Institutions (RNHCI);
- Rural Primary Care Hospitals (RPCHs);
- Home Health Agencies (HHAs);
- Comprehensive Outpatient Rehabilitation Facilities (CORFs);
- Rural Health Clinics (RHCs);
- Federally Qualified Health Centers (FQHCs);
- Outpatient Physical Therapy (OPT) providers; and Independent Renal Dialysis Facilities (RDFs).

B11. What type of providers and suppliers may bill the carrier for flu and PPV vaccinations?

- Physicians
- Suppliers
- Hospices
- Public Health Clinics
- Pharmacists / Pharmacies
- Self Employed Nurses
- Senior Centers
- Shopping Malls
- Non Skilled Nursing Homes
- Assisted Living Facilities
- Mass Immunization Providers

B12. May a registered nurse employed by a physician use the physician's provider number if flu and PPV vaccinations are provided by the nurse in a location other than the physician's office?

No. If the nurse is not working for the physician when the services are provided (e.g., a nurse is "moonlighting," administering flu and PPV vaccinations at a shopping mall at his or her own direction and not that of the physician), the nurse may obtain a provider number and bill the carrier directly. However, if the nurse is working for the physician when the services are provided, the nurse would use the physician's provider number.

B13. May certified Part A providers submit claims to a carrier?

No. With the exception of hospice providers, certified Part A providers must bill their intermediary for this Part B benefit. Hospice providers bill the carrier.

B14. How should nonparticipating provider facilities (e.g., nursing homes) bill Medicare?

Non-Medicare-participating provider facilities bill their local carrier.

B15. May HHAs that have a Medicare-certified component and a non-Medicare certified component elect to furnish the flu and PPV benefit through the non-certified component and bill the Part B carrier?

Yes, for certain circumstances. Billing procedures for HHAs (Billing procedures 473, Rev. 296) are described at: http://cms.hhs.gov/manuals/11_hha/HH00.asp .
When you provide the flu virus vaccine in a mass immunization setting, you do not have the option to pick and choose whom to roster bill for this service. If you are using employees from your certified portion, and as a result will be reflecting these costs on

your cost report, you must bill your Regional Home Health Intermediary (RHHI) on the Form CMS-1450.

If you are using employees from your non-certified portions (employees of another entity that is not certified as part of your HHA), and as a result, payment will not be made on the cost report for these costs, you must obtain a provider number and bill your carrier on the Form CMS-1500.

If employees from both certified and non-certified portions of your facility are used to furnish the vaccine at a single mass immunization site, you must prepare two separate rosters, i.e., one for employees of the certified portion of your facility to be submitted to your RHHI, and one for employees of the non-certified portion of your facility to be submitted to your carrier.

B16. How do carriers handle flu and PPV vaccination claims for Railroad Retirement Board (RRB) beneficiaries?

Carriers will return as unprocessable assigned claims and deny unassigned claims. The physician, non-physician practitioner or supplier must submit the claim to Palmetto GBA (the RRB carrier) at P.O. Box 10066, Augusta, and GA 30999.

Physician presence

B17. Does a physician have to be present when the flu and PPV vaccines are administered?

No. Medicare does not require a physician to be present. However, laws in individual states may require a physician's presence.

Frequency

B18. There has been some confusion about how often a beneficiary can receive a flu vaccination and have it covered by Medicare. If a beneficiary receives a flu vaccination more than once in a 12-month period, will Medicare still pay for it?

Yes. Generally, Medicare pays for one flu vaccination per flu season. This may mean that a beneficiary will receive more than one flu vaccination in a 12-month period. For example, a beneficiary may receive a flu vaccination in January 2003 for the 2002-03 flu season and another flu vaccination in November 2003 for the 2003-04 flu season. In this case, Medicare will pay for both shots because the beneficiary received only one flu shot per season (January and November).

B19. What if a beneficiary needs more than one flu shot in a flu season?

Medicare will pay for more than one flu vaccination per flu season if a physician determines and documents that the vaccination is reasonable and medically necessary.

C. PAYMENT POLICY

Medicare Vaccine/Administration Payment

C1. Why is there such a variation between states and even within states in Medicare reimbursement rates for flu and PPV vaccine and its administration?

Medicare's allowed payment amount for the flu and PPV vaccines is determined as it is for any other drug, i.e., Medicare pays the lower of the actual charge or 95% of the lowest average wholesale price (AWP) as reflected in such sources as the Red Book, Blue Book or Medispan.

Since administration fee schedules are adjusted for each Medicare payment locality, there is a variation in the administration payment amount nationwide. Medicare payment by carriers for the administration of the vaccines is linked to payment for services under the physician fee schedule but is not actually paid under the physician fee schedule. The charge for the administration is the lesser of the actual charge or the fee schedule amount for a comparable injection.

Intermediary payment to a provider for the flu vaccine and its administration is made on the basis of reasonable cost.

Payments for Drugs and Biologicals

Drugs and biologicals not paid on a cost or prospective payment basis are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources, such as the *Red Book*, *Price Alert*, or *Medispan*.

Calculation of the AWP:

1. For a single-source drug or biological, the AWP equals the AWP of the single product.
2. For a multi-source drug or biological, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP. A "brand name" product is defined as a product that is marketed under a labeled name that is other than the general chemical name for the drug or biological.
3. After determining the AWP, multiply it by 0.95. This determines the new drug payment allowance limit. Do not round this payment allowance limit. There is no minimum for this amount.

Example of Flu Vaccine Payment Calculation **Lowest average wholesale price* x 95%** **$84.38/10 = $8.43 x 0.95 = $8.02**			
Product/MFR	**Description**	**NDC**	**AWP****
FluShield (Wyeth-Ayerst)	(Vial, 2002-03 formula) 45 mcg/0.5 ml	00008-0987-01	$84.38
FluZone (Aventis Pasteur)	(M.D.V., Sub-Virion 02-03) 45 mcg/0.5 ml	49281-0372-15	$106.25
Flu Virin (Allscripts)	(M.D.V., 2002-2003) 45 mcg/0.5 ml	66521-0105-10	$87.00*
New rates are published quarterly. These example rates are intended to show the calculation **method, not the actual calculation. The example shown is based on the Spring 2003 quarterly *Red Book* update.			

C2. When will this year's payment rates be set?

Since the Medicare vaccine payment rate is based on the lowest AWP for the current year's vaccines, not the AWP for the previous season, carriers cannot calculate this year's payment rate until AWPs are published in sources, such as *Red Book*, *Price Alert*, or *Medispan*. Carriers update pricing of drugs and biologicals on a *quarterly* basis, therefore, each quarter the vaccine payment rate may increase or decrease depending on that quarter's published AWPs. If the payment decreases, carriers are required to provide at least 30 days notice of the lower rate.

C3. How are the payment rates for the flu and PPV administration determined?

The allowed amount for the administration of the flu and PPV is based on the same rate as the Health Care Procedure Coding System (HCPCS) code 90782 (Injection, sc/im) as priced on the physician fee schedule database. Therefore, the allowable fee for the administration of the flu and/or PPV will vary based on the locality of the provider.

Physician Fee Schedule Formula

= Fee Schedule Amount

The Fee Schedule Amount for a service paid from the physician fee schedule is a product of three numbers:

1. Relative Value Units (RVUs) – this is established nationally for each procedure and will not vary between carriers;
2. Geographic Practice Cost Indices (GPCIs) – this is established nationally for each payment locality. Therefore, this number will change depending on where the service is provided;
3. National Conversion Factor (CF) – this is established nationally and will not vary by carrier.

For each fee schedule service, there are three relative values:

1. A relative value for physician work (RVUw),
2. A relative value for practice expense (RVUpe), and
3. A relative value for malpractice (RVUm).

RVU for Physician Work x GPCI for Physician Work	+	RVU for Practice Expense x GPCI for Practice Expense	+	RVU for Malpractice x GPCI for Malpractice x National CF
RVUw		RVUpe		RVUm

C4. What is the final impact of the change in 2003 reimbursement for vaccine administration?

The Medicare payment for vaccine administration went up an average of $3.74, or 94 per cent, as compared with 2002. A schedule of actual pay rates can be found at: http://cms.hhs.gov/preventiveservices/2j.zip

C5. In the clinic or outpatient setting, is the administration a set fee no matter what it costs to administer the vaccine (PPV and Flu)? Where is the regional variability as far as cost for vaccine; is it the administration or the vaccine cost or both?

For hospital outpatient departments, the payment for administering the vaccine is paid under the hospital outpatient prospective payment system (OPPS). The payment for the vaccine also is paid under the hospital OPPS. Payment rates under the hospital OPPS were based on hospital charge/cost data and are updated annually. Payment rates for the administration of the vaccine itself (i.e., the injection) and the vaccine, as with other services paid under the hospital OPPS, vary based on differences in costs across regions. CMS uses the same factor to adjust other services provided under the hospital OPPS. We also note that the payment rate for the administration of the vaccine when provided in a physician's office is also adjusted for geographic differences in costs. The adjustment for the administration of the vaccine is made using the same factor for services under the physician fee schedule.

C6. Describe the process for updates and changes to the Revisions to Payment Policies. What is legislatively set? What parts can CMS propose changes to?

The formula for determining the update is statutorily defined. CMS sets the relative value of physician services following long-established processes that are described in Medicare regulations. In general, CMS proposes relative values in May for the following year. The proposed rule has a 60-day comment period. Comments are encouraged and considered before the final rule is issued.

C7. Will Medicare's change in payment for vaccine administration affect Medicaid payment?

No. Medicaid sets its own payment rate for immunization based on factors other than Medicare payment.

Collecting Payment

Under Section 114 of the Benefits Improvement and Protection Act of 2000 (BIPA), payment for any drug or biological covered under Part B of Medicare may be made only on an assignment-related basis. Therefore, all physicians, non-physician practitioners, and suppliers who administer the flu virus or the pneumococcal vaccination after February 1, 2001, must take assignment on the claim for the vaccine.

C8. Does the limiting charge provision apply to the flu or PPV benefit?

No. Non-participating physicians and suppliers who do not accept assignment for the *administration* of the flu or PPV benefit may collect their usual charges (i.e., the amount charged a patient who is not a Medicare beneficiary) for the flu and PPV administration.

The beneficiary is responsible for paying the difference between what the physician or supplier charges and the amount Medicare allows for administration. However, all physicians and suppliers, regardless of participation status, must accept assignment of the Medicare vaccine payment rate.

C9. May providers, physicians, and suppliers charge and collect payment from Medicare beneficiaries for the flu or PPV vaccinations?

Non-participating physicians, providers, and suppliers that do not accept assignment on the administration of the vaccines may collect payment from the beneficiary, but they must submit an unassigned claim on the beneficiary's behalf. All physicians, non-physician practitioners and suppliers must accept assignment for the Medicare vaccine payment rate and may not collect payment from the beneficiary for the vaccine.

Participating physicians, non-physician practitioners, and suppliers that accept assignment must bill Medicare if they charge a fee to cover any or all costs related to the provision and/or administration of the flu or PPV vaccine. They may not collect payment from beneficiaries.

C10. May a physician, provider, or supplier charge a Medicare beneficiary more for an immunization than he or she charges a non-Medicare patient?

No. According to Section 1128(b)(6)(A) of the Social Security Act, a physician/supplier may not charge a Medicare beneficiary more for an immunization than they would charge a non-Medicare patient. (For exceptions to this rule, see C16.)

C11. There has been some concern about the confusion caused by providers advertising flu and PPV vaccination as "free." When patients later receive EOMBs, they contact the carrier to report fraudulent billing. Should providers advertise this as a "free" service?

Physicians, providers, and suppliers that accept assignment may advertise that there will be no charge to the beneficiary, but they should make it clear that a claim will be submitted to Medicare on their behalf.

Physicians, providers, and suppliers that do not accept assignment should never advertise the service as free since there could be an out-of-pocket expense for the beneficiary after Medicare has paid at 100 percent of the Medicare-allowed amount.

C12. Is a coinsurance amount or deductible required for the flu and PPV vaccine benefits?

No. Medicare pays 100 percent of the Medicare approved charge or the submitted charge, whichever is lower. Neither the $100 annual deductible nor the 20 percent coinsurance applies.

C13. May a physician, provider, or supplier collect payment for an immunization from a beneficiary and instruct the beneficiary to submit the claim to Medicare for payment?

No. Section 1848 (g)(4)(A) of the Social Security Act requires that physicians, providers, and suppliers submit a claim for services to Medicare on the beneficiary's behalf.

C14. May providers, physicians, and suppliers submit claims for the flu and PPV benefit to Medicare if they provide the benefits free of charge or on a sliding fee scale to other patients?

Non-governmental entities (providers, physicians, or suppliers) that provide immunizations free of charge to all patients, regardless of their ability to pay, must provide the benefit free of charge to Medicare beneficiaries and may not bill Medicare.

However, a non-governmental entity that does not charge patients who are unable to pay, or reduces its charge for patients of limited means (sliding fee scale), but does expect to be paid if a patient has health insurance which covers the items or services provided, may bill Medicare and receive Medicare program payment.

State and local government entities, such as public health clinics, may bill Medicare for immunizations given to beneficiaries even if they provide immunizations free to all patients, regardless of their ability to pay.

C15. Historically, some entities that have provided mass immunization programs have not charged patients the full cost of the vaccine and/or its administration because they have subsidized part of the cost from their budgets. Instead, they have requested a specific dollar "donation" that covers part of the cost of the vaccination. These entities do not then submit a claim to Medicare on behalf of the beneficiary. Is this an acceptable practice?

No. Since the flu and PPV benefits do not require any beneficiary coinsurance or deductible, a Medicare beneficiary has a right to receive this benefit without incurring any out-of-pocket expense. In addition, the entity is required by law to submit a claim to Medicare on behalf of the beneficiary.

The entity may bill Medicare for the amount that is not subsidized from its budget. For example, an entity that incurs a cost of $7.50 per flu shot and pays $2.50 of the cost from its budget may bill the carrier the $5.00 cost which is not paid out of its budget.

C16. How should carriers handle flu and PPV claims that are submitted by beneficiaries?

Though Section 1848(g)(4)(A) of the Social Security Act requires physicians and suppliers to submit Part B Medicare claims for beneficiaries for services furnished on or after September 1, 1990, carriers should accept and process claims submitted by beneficiaries under procedures that are applied in other situations in which unassigned claims submitted on Form CMS-1490s are received from beneficiaries. Carriers should use the provider specific information included on receipts submitted by beneficiaries to construct a skeleton provider record and assign a temporary provider number for the entity that furnished the service. Carriers should need minimal information to assign a provider number and establish/create a provider file record.

Carriers should also initiate appropriate educational contacts with the providers concerning Medicare billing requirements for Part B services covered, obtain a formal provider application, and assign a provider identification number.

C17. Does the 5 percent payment reduction for physicians who do not accept assignment for the administration of the vaccine apply to the flu and PPV vaccination benefit?

No. Only items and services covered under limiting charge are subject to the 5 percent payment reduction.

C18. If a physician sees a beneficiary for the sole purpose of administering a flu or PPV vaccination, may he or she routinely bill for an office visit?

No. If a physician sees a beneficiary for the sole purpose of administering a flu or PPV vaccination, the physician may only bill for the administration and vaccine. However, if a patient actually receives reasonable and medically necessary services constituting an "office visit" level of service, the physician may bill for the office visit, the vaccine and the administration of the vaccine.

C19. Must carriers generate the Explanation of Medicare Benefits (EOMB) or Medicare Summary Notice (MSN) for beneficiaries for the PPV and flu vaccinations?

Effective April 1, 1999, an EOMB or MSN must be generated for PPV and flu vaccines and their administration.

C20. Will Medicare pay for claims for flu and PPV shots that are old?

Immunizers have at least 27 months from the date of service to file claims to the Medicare Program. All claims not submitted within the first 12 months, however, will have a 10% reduction in payment.

Billing Procedures

C21. Can providers bill for services related to counseling and education?

No. Medicare does not pay solely for counseling and education for flu shots. If Medicare-covered services are provided during the visit in which the immunization is given, the physician may code and bill those other medically necessary services, including evaluation and management services. A frequently asked question (FAQ) section on the CMS website describes the use of these codes in detail. The website is located at: http://cms.hhs.gov/medlearn/emdoc.asp

C22. What information is needed on the CMS-1450 and CMS-1500 to bill for the flu and PPV vaccinations?

All data fields that are required for any Part A or Part B claim are required for the vaccines and their administration. Physicians, non-physician practitioners, and suppliers should bill in accordance with the instructions within provider manuals provided by their Medicare carrier. Additionally, coding specific to these benefits is required. The forms are available online at: http://www.cms.hhs.gov/providers/edi/edi5.asp.

C23. If the Health Insurance Claim Number (HICN) is incorrect, will the contractor contact the provider or the beneficiary to determine the correct number?

Providers and suppliers are responsible for filling out required items on the claims forms with correct information from beneficiaries. If necessary, the "Date of Birth" column on the roster should, along with other data elements, provide sufficient beneficiary information for the contractor to resolve incorrect HICNs. However, if through other information on the claim or through beneficiary contact the contractor cannot resolve the problem, the claim will be rejected.

Home Health Agencies

C24. For Home Health Associations (HHAs), are vaccines paid under cost reimbursement?

Yes. Medicare pays for vaccine on a cost-reimbursement basis on the cost report.

C25. For HHAs, will interim rates be paid to home health agencies for their immunization expenses?

Yes. Provider Reimbursement Manual, Part 1, section 2406, provides for the percentage of billed charges interim payment method for cost reimbursed services by HHAs. As this section explains, the intermediary, with documentation from the HHA, estimates the

annual Medicare cost-reimbursement for the vaccines furnished to beneficiaries divided by estimated charges for those drugs, applying the resulting interim rate to the vaccine charges on submitted bills. Although the lower of costs or charges provision does not apply to an HHA's Medicare prospective payments, it does apply to items or services paid on a cost basis. Therefore, should the estimated charges for the vaccines be less than estimated cost, the interim rate cannot exceed 100 percent (section 2406.6). Interim payments are to approximate as closely as possible reimbursement that will be made on the cost report. Therefore, an intermediary is expected to monitor the rate and make adjustments as necessary, and a provider may always furnish information to its intermediary if it can support that the actual costs are significantly different from the payment it is receiving via its interim payments. Finally, as you indicated, adjustment is made with a payout or recovery as necessary on final settlement (an, as appropriate, through a tentative retroactive adjustment on the submitted cost report).

C26. How should HHAs represent the costs for vaccines and administration on their cost reports?

The cost of the vaccines is shown separately on the cost report (for free-standing HHA on FORM CMS-1728, Worksheet A, line 13, Drugs, later further identified On Worksheet C between drugs to which Medicare deductible and coinsurance (D&C) apply (the osteoporosis drug) and drugs to which D&C do not apply (influenza and pneumococcal vaccines)). Provider documentation to support the costs incurred is no different than for any other cost claimed on the cost report or different from what has been expected for these vaccines in the past. An HHA must have support for its costs when asked by the FI for that information. Administration of the vaccines during a visit made for reasons other than administration of a vaccine is part of the visit cost paid under the prospective payment system (PPS) and is not paid separately. The cost of administration made outside the context of home health visits and which is documented as necessary in administering the vaccines can be included in the drugs cost center along with the vaccine cost. Cost finding (allocation of overhead costs) is done the same as for any other cost center, whether paid via PPS or on a cost basis. Statistics for the drugs cost center will draw overhead (general service) costs as appropriate. For example, the accumulated cost statistic draws administrative and general costs, and the square footage statistic draws capital and plant operation costs as appropriate.

C27. Are there any specific reasonable cost limits or guidelines applied to vaccination costs that could result in payments less than a HHA's actual costs for furnishing services to Medicare beneficiaries?

Other than application of the lower of costs or charges provision as discussed in No. 1 above, Medicare recognizes the reasonable, allowable cost for vaccines. If an HHA's intermediary believes that the HHA has unreasonably incurred cost for the vaccines—or otherwise has not been a prudent buyer –it is up to the HHA to support that it was prudent and that the costs are reasonable. If it cannot, the intermediary is expected not to recognize what it finds to be the unreasonable portion of the incurred cost.

C28. If vaccine demand is less than that anticipated, and vaccine cannot be returned, resold or used elsewhere, may the cost of unused vaccine be considered as a reasonable cost?

No. CMS would only pay for vaccines actually administered. We would not pay for vaccines bought by hospitals or HHAs but never administered. For instance, a provider may order 1,000 vaccines but only provide 700 immunizations because of lower than anticipated demand. CMS would recognize only the cost of the 700 vaccines that are administered. We would not recognize the cost of the 300 excess unused vaccines.

Health Insurance Portability and Accountability Act (HIPAA)

C29. What is HIPAA?

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 are intended to reduce the costs and administrative burdens of health care by making possible the standardized, electronic transmission of many administrative and financial transactions that are currently carried out manually on paper. HIPAA is the first step toward building an e-commerce platform for exchanging health care information and will improve the effectiveness and efficiency of the health care industry in general, by simplifying the administration of the system and enabling the efficient electronic transmission of certain health information.

C30. What impact do HIPAA requirements have on flu and PPV billing?

HIPAA Administrative Simplification required all "covered entities" that transmit any health information in electronic form to comply with the regulations regarding standard electronic transactions and code sets by October 16, 2002 (except small health plans), unless a covered entity filed an extension form by October 15, 2002. In that case covered entities that filed an extension request have until October 16, 2003 to comply with the regulations. Failure to comply with federal HIPAA deadlines may impact Medicare reimbursements. To determine whether you are a covered entity, go to the CMS website at www.cms.hhs.gov/hipaa/hipaa2 or call the HIPAA Administrative Simplification Hotline at 1-866-282-0659.

C31. Who/what is a "covered entity" for HIPAA?

All health plans, health care clearinghouses, and providers who transmit health information electronically are classified by HIPAA as covered entities. These include physicians, dentists, pharmacies, nursing homes, hospitals, hospices, durable medical equipment suppliers, home health agencies, and others.

C32. How long will paper claims for flu and PPV continue to be paid by Medicare?

Paper claims for Medicare-covered vaccinations are now exempt under a ruling published August 15, 2003. To reference the ruling, please go to: http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-20955.pdf

C33. Where can we find additional information related to HIPAA?

Information about HIPAA and its requirements is available through CMS, industry groups, associations, and other organizations. Below are several sources:

Websites:

http://www.cms.hhs.gov/hipaa/hipaa2 – website for Centers for Medicare & Medicaid Services (CMS)
http://aspe.os.dhhs.gov/admnsimp – DHHS Administrative Simplification website
http://www.wpc-edi.com/hipaa and http://www.hipaa-dsmo.org/ – Washington Publishing Company, download free implementation guides, Q&As, etc.

Email: AskHIPAA@cms.hhs.gov – ask questions of the CMS HIPAA experts
Telephone: HIPAA Administrative Simplification Hotline, 1-866-282-0659
Questions regarding HIPAA privacy requirements should be directed to the U.S. Department of Health & Human Services Office for Civil Rights, 1-866-627-7748 or its website at http://www.hhs.gov/ocr/hipaa .

(See Section D for roster billing procedures)

PART A – Fiscal Intermediaries

C34. Who bills for the flu and PPV vaccination when it is furnished to a dialysis patient of a hospital or hospital-based renal dialysis facility?

Regardless of where the vaccine is administered to a dialysis patient of a hospital, the hospital bills the intermediary using bill type 13X.

C35. What bill types for claims billed to the intermediary are applicable for the flu and PPV benefits?

Applicable bill types are: 13X, 22X, 23X, 34X, 71X (provider-based RHCs only), 72X, 73X (provider-based FQHCs only), 74X, 75X, and 85X.

C36. Independent Rural Health Clinics (RHCs) are required to use revenue code 521 in order to bill. How should they show the charge for the vaccines and their administration on the CMS-1450?

RHCs follow guidelines in subsection 614 of the RHC/FQHC Manual. They do not include charges for the vaccines or their administration on the CMS-1450. Payment is made at cost settlement.

C37. For claims billed to the intermediary, are providers allowed to use therapy revenue codes on the flu and PPV claims?

Providers bill for the vaccines using revenue code 636 and for the administration using revenue code 771. If therapy services are also provided, they can be reflected on the same claim with the vaccines and their administration.

C38. Should Part A shared systems maintainers allow condition code "A6" or special program indicator "06" on vaccine claims?

Yes.
Condition code A6 is used to indicate services not subject to deductible and coinsurance.

C39. For inpatient hospital and inpatient skilled nursing facilities that bill the intermediary, what revenue code is used for the administration?

All providers that bill the intermediary for the flu and PPV vaccines report the administration under revenue code 771.

C40. What bill types do hospitals and skilled nursing facilities that bill the intermediary report for inpatients who receive this benefit?

Medicare hospitals bill for the vaccines under bill type 13X for their inpatients and skilled nursing facilities bill for the vaccines under bill type 22X.

PART B – Carriers

C41. What should be entered in item 11 of the CMS-1500 when Medicare is known to be the secondary payer?

For all flu vaccination claims submitted to a carrier, item 11 of the preprinted CMS-1500 should show "NONE."

C42. Sometimes an entity receives donated vaccine or receives donated services for the administration of the vaccine. In these cases, may the provider bill Medicare for the portion of the vaccination that was not donated?

Yes.

C43. Is a Unique Provider Identification Number (UPIN) required on the CMS-1500 for PPV claims?

As a physician's order is no longer required for PPV vaccinations, the UPIN of the physician is no longer required on the CMS-1500.

Procedure Codes

C44. What are the specific codes that must be used?

The following codes are used for flu vaccinations:

CPT / HCPCS Code	Description
90657	Influenza virus vaccine, split virus, for children 6-35 months of age, for intramuscular use
90658	Influenza virus vaccine, split virus, for use in individuals 3 years of age and above, for intramuscular use
G0008	Administration of Influenza Virus Vaccine

Diagnosis Code	Description
V04.8*	Influenza Vaccination (For use **before 10/01/03**)
V04.81	Influenza Vaccination (For use **on or after 10/01/03**)

*After 10/01/03, this code will be revised to be a sub-category for the need for prophylactic vaccination and inoculation against other viral diseases

Providers are responsible for submitting the correct codes on their claims. The code should be chosen based on the description of the drug and the age of the patient. Codes are not interchangeable.

The following codes are used for PPV vaccinations:

CPT / HCPCS Code	Description

90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, for use in individuals 2 years or older, for subcutaneous or intramuscular use
G0009	Administration of pneumococcal vaccine

Diagnosis Code	Description
V03.82	Pneumococcal Vaccination

C45. If a beneficiary receives both the flu vaccine and the PPV vaccine on the same day, will Medicare pay twice for the administration fee?

Yes.

C46. May other charges be listed on the same bill with the flu and PPV vaccinations?

For normal billing procedures (not roster billing), other charges may be listed on the same bill as flu and PPV vaccinations. However, there must be separate coding for the additional charge(s).

C47. If we choose not to roster bill and only bill on the UB 92, will Medicare track the usage from the revenue code?

Medicare will track using HCPCS and revenue codes on the UB-92.

C48. As a provider, if I choose not to roster bill and only bill on the UB-92, will Medicare track the usage from the revenue code 771?

HCPCS codes would be used to track vaccine services regardless of whether they are billed on a roster or UB. All rosters are converted to UBs by the intermediary. The revenue code alone would not provide sufficient information to identify the vaccine.

C49. I noticed on a recent Medicare bulletin that vaccines are no longer reimbursed under OPPS, but are reimbursed according to reasonable cost. How will the reimbursement be calculated?

Each provider is assigned an interim rate which is applied to charges for items subject to reasonable cost reimbursement and that is the amount that is payable on an interim claim by claim basis subject to any applicable deductibles or coinsurance. Final payment is then made via the cost settlement.

D. MASS IMMUNIZERS / ROSTER BILLERS

Note: Although these questions primarily concern mass immunizers, they may apply to any entity immunizing Medicare beneficiaries.

Definition

D1. What is a mass immunizer?

As used by CMS, the term "mass immunizer" is defined in the following manner:

- A mass immunizer generally offers flu and/or PPV vaccinations to a large number of individuals (the general public or members of a specific group, such as residents of a retirement community).
- A mass immunizer may be a traditional Medicare provider or supplier such as a hospital outpatient department or may be a nontraditional provider or supplier such as a senior citizen's center, a public health clinic, community pharmacy or supermarket.
- A mass immunizer submits claims for immunizations on roster bills.
- Mass immunizers must accept assignment.

Enrollment Requirements

Note: This enrollment process currently applies only to entities that will (1) bill a carrier; (2) use roster bills; and (3) bill only for flu and/or PPV vaccinations.

D2. Do providers and suppliers that want to mass immunize and submit claims to Medicare on roster bills have to enroll in the Medicare program?

Yes. Providers and suppliers must enroll in Medicare even if mass immunizations are the only service they will provide to Medicare beneficiaries. They can enroll by filling out the CMS-855, the Provider/Supplier Enrollment application. Providers and suppliers who wish to roster bill for mass immunizations should contact the Medicare carrier servicing their area for a copy of the enrollment application and special instructions for mass immunizers. **Providers and suppliers who will not provide other covered services to Medicare beneficiaries complete only the portion of the enrollment form that applies to mass immunizers.**

D3. If a provider or supplier already has a Medicare provider number for non-immunization services that they provide, do they need to obtain a new provider number in order to use the roster billing process for the flu and/or PPV services that they provide?

No. Providers and suppliers may use their existing provider numbers and use the roster billing process as long as they provide the flu and/or PPV service to multiple beneficiaries and agree to accept assignment on the service.

D4. Does a corporate entity with numerous locations have to get a Medicare provider number for each location?

Reimbursement for the administration of the flu and PPV is based on the locality of the provider. Therefore, if the practice locations are in different payment localities, then it would be necessary for each to obtain a separate Medicare provider number for each practice location. The only exception to this is an entity that participates in the Centralized Billing program.

D5. Why enroll providers if they are going to provide mass immunizations to Medicare beneficiaries only once a year?

Although CMS wants to make it as easy as possible for providers and suppliers to immunize Medicare beneficiaries and bill Medicare, it must ensure that those providers who wish to enroll in the Medicare program are qualified providers, receive a provider number, and receive the proper payment.

Billing Procedures

D6. What impact do HIPPA requirements have on electronic Mass Immunizer Roster Billing?

Roster billing is a streamlined process for submitting health care claims for large groups of individuals usually for flu and/or PPV vaccinations for which HIPPA adopted an electronic standard, the ASC X12N 837. Roster billing can be done electronically or via paper. When conducting roster billing electronically, mass immunizer providers are required to use the HIPPA-adopted ASC X12N 837 claim standard.

D7. Can roster billing be conducted on paper after October 16, 2003?

Paper claims for Medicare-covered vaccinations are now exempt under a ruling published August 15, 2003. To reference the ruling, please go to:
http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-20955.pdf

D8. How many beneficiaries per day must be vaccinated in order for the roster billing procedure to be used?

Generally, for institutional claims only, five beneficiaries per day must be vaccinated in order to roster bill. However, this requirement is waived for inpatient hospitals that mass immunize and utilize the roster billing method.

Effective July 1, 1998, only for provider/supplier claims that are submitted to the carrier for processing, immunization of at least five beneficiaries on the same date is no longer required for any individual or entity to qualify for roster billing. However, the rosters should not be used for single patient bills and the date of service for each vaccination administered must be entered.

D9. If providers/suppliers enroll in Medicare for the purpose of roster billing for mass immunizations only, may they bill Medicare for other Part B services?

No. Providers/suppliers who wish to bill for other Part B services must enroll as a regular provider or supplier by completing the entire CMS-855.

D10. Can mass immunizers bill for services relating to counseling and education?

No. Mass immunizers are a provider-type created under Medicare solely to facilitate mass immunization, not to provide other services. (Physicians may bill for additional medically necessary services. See C22.)

D11. May an individual or entity providing both PPV and flu virus vaccinations to the beneficiaries submit a single CMS-1450 or CMS-1500 that contains the information for both the PPV and flu vaccinations and a single roster bill that contains the names of the beneficiaries who received both vaccinations?

No. Individuals and entities submitting claims for PPV and flu virus vaccinations must submit a separate CMS-1450 or CMS-1500 for each type of vaccination. Each CMS-1450 or CMS-1500 must have an attached roster bill listing the beneficiaries who received that type of vaccination. Each roster bill must also contain all other information required on a roster bill.

D12. Are the roster bills used for flu and PPV vaccinations identical?

No. The following reminder to providers must be printed on the PPV roster bill:

WARNING: Ask beneficiaries if they have been vaccinated with PPV.

- Rely on patients' memory to determine prior vaccination status.
- If patients are uncertain whether they have been vaccinated within the past 5 years, administer the vaccine.
- If patients are certain they have been vaccinated within the past 5 years, do not revaccinate.

D13. What blocks on the CMS-1500 can be preprinted for providers using roster billing for flu and/or PPV vaccine and/or administration claims?

The following blocks can be preprinted on a modified CMS-1500 form:

Item 1: An X in the Medicare block
Item 2: (Patient's Name): "SEE ATTACHED ROSTER"
Item 11: (Insured's Policy Group or FECA Number): "NONE"
Item 20: (Outside Lab?): An "X" in the "NO" block
Item 21: (Diagnosis or Nature of Illness):
Line 1:
PPV: "V03.82"
Influenza Virus: "V04.8"
Item 24B: (Place of Service (POS)):
Line 1: "60"
Line 2: "60"
NOTE: POS code "60" must be used for roster billing
Item 24D: (Procedures, Services or Supplies):
Line 1:
PPV: "90732"
Influenza Virus: "90659"
Line 2:
PPV: "G0009"
Influenza Virus: "G0008"
Item 24E: (Diagnosis Code):
Lines 1 and 2: "1"
Item 24F: ($ Charges): The entity must enter the charge for each listed service. If the entity is not charging for the vaccine or its administration, it should enter 0.00 or "NC" (no charge) on the appropriate line for that item.
Item 27: (Accept Assignment): An "X" in the YES block
Item 29: (Amount Paid): "$0.00"
Item 31: (Signature of Physician or Supplier): The entity's representative must sign the modified form CMS-1500.
Item 32: (Name and Address of Facility): N/A
Item 33: (Physician's, Supplier's Billing Name): If the provider number is not shown on the roster billing form, the entity must complete this item to include the Provider Identification Number (not the Unique Provider Identification Number) or Group Number as appropriate.

D14. Do providers show the charge for one service or the total for all patients in block 24F of the modified CMS-1500?

Providers should show the unit cost, since carriers will have to replicate the claim for each beneficiary listed on the roster.

D15. What information needs to be submitted on a patient roster form that will be attached to a preprinted CMS-1500 under the roster billing procedure?

The following should be included on the roster form: Patient Name and Address; Health Insurance Claim Number; Date of Birth; Sex; Date of Service; Signature or stamped "Signature on File"; and Provider's Name and Identification Number.

Some carriers allow providers/suppliers to develop their own patient roster forms that contain the minimum data as reflected above, while others do not. Providers/suppliers should contact their carrier to learn their particular carrier's practice regarding patient roster forms.

D16. What is the meaning of "signature on file?"

For all institutional providers that roster bill from inpatient or outpatient departments, and for all other providers outside of the institutional setting that roster bill, a stamped "signature on file" qualifies as an actual signature on a roster claim form provided that the provider has a signed authorization on file to bill Medicare for services rendered. In this situation, the provider is not required to obtain the patient signature on the roster, but instead has the option of reporting "signature on file."

D17. What would the carrier do if a roster bill were received incomplete or incorrect?

The carrier would deny or reject the claim as unprocessable.

D18. May hospitals and other entities that bill intermediaries use the "signature on file" designation on a roster bill?

Yes. Inpatient/outpatient departments of hospitals and outpatient departments of other providers may use a signature on file stamp or notation if they have access to a signature on file in the beneficiary's record.

D19. May other services be listed along with the flu or PPV vaccine and administration on the modified CMS-1500?

No. Other covered services are subject to more comprehensive data requirements, which the roster billing process is not designed to accommodate. Other services should be billed using normal Part B claims filing procedures and forms.

D20. Is electronic billing available for roster-billed claims?

Not all contractors offer electronic roster billing software. However, if available, contractors should offer low or no-cost software for providers to use when roster billing electronically.

D21. What place of service code should be used for PHCs that bill carriers for the flu and PPV vaccines and their administration?

PHCs should use place of service code "60," public health or welfare agencies (federal, state, and local).

D22. If a beneficiary receives a flu or PPV vaccination shot at a mobile unit brought to a senior center or parking lot of a mall, what place of service code should be used?

A PHC-affiliated mobile unit should use POS code "71" unless vaccinations are administered in a mass immunization setting. ALL entities that administer vaccinations in a mass immunization setting should use POS code "60" (Mass Immunization Center), no matter the setting. A mobile unit not affiliated with a PHC and not acting as a mass immunization setting should use "99" (other).

D23. In some instances, two entities, such as a grocery store and a pharmacy, jointly sponsor a vaccination clinic, and each is reluctant to accept responsibility for billing. What are the criteria for determining the responsible party?

Assuming that a charge is made for both the vaccine and its administration, the entity that furnishes the vaccine and the entity that administers the vaccine are each required to submit claims. Both parties must file separately for the specific component furnished for which a charge was made.

When billing only for the administration, billers should indicate in block 24 of the CMS-1500 that they did not furnish the vaccine. For roster billed claims, this can be accomplished by lining through the preprinted item 24 line item component that was not furnished by the billing entity or individual.

Hospital Inpatient Roster Billing

D24. Some hospitals have concerns about reimbursement for flu and pneumococcal vaccines administered during hospitalization. Are these vaccinations covered by the DRG flat rate, or reimbursed separately?

Medicare does pay for both influenza and pneumococcal vaccines above the DRG rate for patients vaccinated in the hospital. For both vaccines, hospitals may roster bill. There is no co-pay or deductible for either vaccine.

D25. What is the procedure for billing inpatient vaccinations?

Yes. All instructions are in section 3660.7 of the intermediary manual. Reference to hospital inpatient billing is in subsection I on page 6-341.3.
The hospital manual also has these instructions in section 435, subsection F, page 4-251.

A hospital can bill for an inpatient of a hospital using a 13X bill type using the date of discharge as the date the vaccine and its administration was given. This will avoid editing in CWF. You may also roster bill in a hospital inpatient setting. There are certain criteria for that:

1. You do not have to wait until patients are discharged.

2. Roster should reflect the actual date of service.

3. Requirement to provide the vaccine to five or more patients at the same time to meet the requirement for mass immunizers will be waived when vaccines are provided to inpatients. The roster may contain fewer than 5 patients or fewer than 5 patients on the date of discharge and the roster must contain information indicating that the vaccine was provided to inpatients to avoid questioning regarding the number of patients or various dates.

E. CENTRALIZED BILLING

E1. What is centralized billing?

Centralized billing is a process in which a provider, who is a mass immunizer for flu and pneumococcal (PPV) immunizations, can send all their flu and PPV claims to a single carrier for payment regardless of the geographic locality in which the vaccination was administered.

E2. How are claims that are submitted through the centralized billing program reimbursed?

The administration of the vaccinations will be reimbursed per the Medicare Physician Fee Schedule (MPFS) for the appropriate locality. The vaccines will be reimbursed at the standard method used by Medicare for reimbursement of drugs and biologicals, which is the lower of cost or 95 percent of the Average Wholesale Price (AWP).

E3. How can I participate in this program?

Multi-state mass immunizers interested in centralized billing must contact CMS Central Office (CO) in writing at the following address by June 1 of each year in order to participate in this program for the upcoming flu season.

Division of Practitioner Claims Processing
Provider Billing and Education Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C4-11-27
Baltimore, MD 21244

E4. Is there any particular information that is required in the written request to participate in the centralized billing program?

Yes, the information requested below must be included with the multi-state mass immunizer's request to participate in centralized billing:

- estimates for the number of beneficiaries who will receive flu vaccinations;
- Estimates for the number of beneficiaries who will receive PPV vaccinations;
- The approximate dates for when the vaccinations will be given;
- A list of the states in which flu and PPV clinics will be held;
- The type of services generally provided by your corporation (e.g., ambulance, home health, or visiting nurse); and,

- Whether the nurses who will administer the flu and PPV vaccinations are employees of your corporation or will be hired by your corporation specifically for the purpose of administering flu and PPV vaccinations.

E5. Is there a particular carrier that centralized billing claims should be submitted to?

Yes. Upon acceptance into the program as a centralized biller, you will be notified by the carrier that will be processing the claim. Claims should not be submitted to the carrier in conjunction with this program until the provider has received written notification of acceptance into the centralized billing program from CMS. Providers must apply annually to participate in the program.

E6. Are there any specific criteria associated with centralized billing?

Yes, by agreeing to participate in the centralized billing program, providers agree to abide by the following criteria:

- A mass immunizer must be operating in at least three payment localities for which there are three different carriers processing claims.
- Individuals and entities providing the vaccine and administration must be properly licensed in the state in which the immunizations are given.
- Multi-state mass immunizers must agree to accept assignment (i.e., they must agree to accept the amount that Medicare pays for the vaccine and the administration). Since there is no coinsurance or deductible for the flu and PPV benefit, accepting assignment means that Medicare beneficiaries cannot be charged for the vaccination, i.e., beneficiaries may not incur any out-of-pocket expense. For example, a drugstore may not charge a Medicare beneficiary $10 for a flu vaccination and give the beneficiary a coupon for $10 to be used in the drugstore. This practice is unacceptable.
- The carrier assigned to process the claims for centralized billing will be chosen at the discretion of CMS based on such considerations as workload, user-friendly software developed by the contractor for billing claims, and overall performance.
- The payment rates for the administration of the vaccinations will be based on the MPFS for the appropriate year. Payment made through the MPFS is based on geographic locality. Therefore, the multi-state mass immunizer must be willing to accept that payments received may vary based on the geographic locality where the service was performed.
- The payment rates for the vaccines will be determined by the standard method used by Medicare for reimbursement of drugs and biologicals, which is based on the lower of cost or 95 percent of the AWP.
- Multi-state mass immunizers must agree to submit their claims in an electronic media claims standard format using either the National Standard Format (NSF) or American National Standards Institute (ANSI) X12.837 format. Paper claims will not be accepted.

- In addition to normal roster billing instructions, multi-state mass immunizers must complete on the electronic format, the area that corresponds to Item 32 (Name and Address of Facility, including ZIP code) on Form CMS-1500, for the carrier to be able to pay correctly by geographic locality.
- Multi-state mass immunizers must obtain certain information for each beneficiary including name, health insurance number, date of birth, sex, and signature. The assigned Medicare carrier must be contacted prior to the season for exact requirements. The responsibility lies with the multi-state mass immunizer to submit correct beneficiary Medicare information (including the beneficiary's Medicare Health Insurance Claim Number) since the carrier will not be able to process incomplete or incorrect claims.
- Multi-state mass immunizers must obtain an address for each beneficiary so that the carrier can send an Explanation of Medicare Benefits (EOMB) or Medicare Summary Notice (MSN) to the beneficiary. Beneficiaries are sometimes confused when they receive an EOMB or MSN from a carrier other than the carrier that normally processes their claims, which results in unnecessary beneficiary inquiries to the Medicare carrier. Therefore, multi-state mass immunizers must provide every beneficiary receiving a flu or PPV vaccination with the name of the carrier selected by CMS. This notification must be in writing, in the form of a brochure or handout, and must be provided to each beneficiary at the time he or she receives the vaccination.
- Multi-state mass immunizers must retain roster bills with beneficiary signatures at their permanent location for a time period consistent with Medicare regulations. The Medicare carrier selected to process the claims can provide this information.
- Though multi-state mass immunizers may already have a Medicare provider number, for purposes of centralized billing, they must also obtain a provider number from the carrier selected by CMS to process the flu and PPV claims. This can be done by completing Form CMS-855 (Provider Enrollment Application), which can be obtained from that carrier.
- If a multi-state mass immunizer's request for centralized billing is approved, the approval is limited to the upcoming flu season. It is the responsibility of the multi-state mass immunizers to reapply to the CMS CO for approval each year by June 1 for the year prior to the beginning of the flu season for which they wish to bill. Claims submitted without approval will be denied.
- Each year the multi-state mass immunizers must contact the assigned carrier to verify understanding of the coverage policy for the administration of the PPV vaccine, and for a copy of the warning language that is required on the roster bill.
- The multi-state mass immunizer will be responsible for providing the beneficiary with a record of the PPV vaccination.

F. MANAGED CARE

F1. Health Maintenance Organizations (HMOs) under a risk contract with CMS provided the vaccine during a health fair to both their members and other Medicare beneficiaries not enrolled in the HMO for a fee. How will these HMOs bill Medicare for flu and PPV vaccines administered to fee-for-service beneficiaries not enrolled in their HMO? Do carriers issue a provider number under the streamlined procedure and process the claims using the simplified process, coding the specialty designation as "99" (Unknown Physician Specialty)?

HMOs that furnish flu and PPV vaccinations to non-member Medicare beneficiaries bill the carrier. The carrier will issue a provider number to the HMO. Specialty code 99 is acceptable for an HMO. The HMO may use roster billing only if vaccinations are the sole Medicare-covered services furnished by the HMO to non-member Medicare patients.

F2. Beneficiaries have difficulty distinguishing between cost and risk HMOs. What is the distinction between cost and risk HMOs? How does this affect the beneficiary?

Beneficiaries enrolled in a risk HMO must receive all of their care through the plan's doctors, hospitals, and other health care providers, except for emergency care and unforeseen out-of-area care. This is referred to as "locked-in." Beneficiaries enrolled in a cost HMO may choose to receive all of their care through the plan's doctors, hospitals, and other health care providers or may choose to receive their medical care from any other health care provider who participates in the Medicare program. However, if beneficiaries do not choose a plan health care provider, they are responsible for paying all of the coinsurance and deductibles associated with such care.

F3. Will beneficiaries in a "lock-in" HMO plan be able to receive vaccines at other locations?

No. Beneficiaries enrolled in Medicare contracted HMOs generally must obtain the shot through plan providers, or they will have to pay for the shot. HMO enrollees should check with their plan to determine if they are "locked-in" to plan providers for their flu and PPV vaccinations. If not "locked-in," the beneficiary may obtain the flu or PPV vaccination from any qualified provider.

F4. What should carriers do if providers submit claims for beneficiaries who are "locked-in" to their HMO when the vaccine is furnished by a facility or provider outside of their HMO?

Medicare will not reimburse a non-HMO provider for flu or PPV vaccinations for beneficiaries enrolled in risk HMOs. Medicare has already paid the HMO to provide this service.

F5. If a beneficiary who belongs to a risk HMO receives a flu or PPV vaccination from a fee-for-service provider, who is responsible for the payment, the beneficiary or the fee-for-service provider?

Beneficiaries will have to pay for the vaccination out-of-pocket.

F6. Is the beneficiary responsible for a co-payment when a vaccine is provided at HMOs where a co-payment is required for any office visit?

Yes. The HMO is permitted to charge a co-payment. However, CMS has asked managed care plans to waive co-payments for flu and vaccinations, effective January 1, 1998.

TERMS AND DEFINITIONS

Advisory Committee on Immunization Practices (ACIP) – The ACIP develops written recommendations for the routine administration of vaccines to pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. ACIP is the only entity in the federal government that makes such recommendations.

Assignment – The doctor or person performing the service receives the Medicare payment. The provider of services accepts the amount Medicare allows as his total charge. The beneficiary is responsible for any deductible and the 20 percent coinsurance.

Assigned claim – See assignment.

Beneficiary – an individual who is entitled to Medicare Part A and/or Medicare Part B.

Billing Providers – the provider who submits a claim for payment on services he/she has performed or, in some cases, the group, such as a clinic, bills for the performing providers within the group.

Carrier – the company contracted with the federal government to handle the Medicare Part B program for a particular state.

Centers for Medicare & Medicaid Services (CMS) – federal agency that administers the Medicare, Medicaid and SCHIP programs.

Centralized billing – optional program for providers who qualify to enroll with Medicare as the provider type, "mass immunizer." Additional criteria must also be met.

CMS 1450 – form used to bill the fiscal intermediary for services provided to a Medicare beneficiary.

CMS 1500 – form used to bill the carrier for services provided to a Medicare beneficiary.

Coinsurance – the 20 percent difference between the allowed amount and the 80 percent that is reimbursable under the Medicare program.

Deductible – the amount that must be met each calendar year from allowed medical expenses before Medicare Part B payment will be made. This amount is the responsibility of the beneficiary.

Electronic billing software – software available for transmitting electronic claims to Medicare.

Explanation of Medical Benefits (EOMBs) – see Medicare Summary Notice (MSN)

Fiscal Intermediary (FI) – the entity under contract with CMS for administering Part A of the Medicare program.

Government entities (such as public health clinics) – may bill Medicare for PPV, hepatitis B, and flu vaccine administered to Medicare beneficiaries when services are rendered free of charge to non-Medicare beneficiaries.

Health Care Procedure Coding System (HCPCS) – a listing of codes, modifiers, and descriptive terminology used for reporting the provision of medical supplies, materials, injections, Durable Medical Equipment (DME), prosthetic devices, and certain services and procedures to Medicare.

Health insurance claim number – the 10- or 11-digit number assigned by Medicare to each beneficiary.

Health Maintenance Organization (HMO) – a health care organization that acts both as insurer and provider of comprehensive but specified medical services. A defined set of physicians provides services to a voluntarily enrolled population for a prospective per capita amount (i.e., by capitation). Prepaid group practices and individual practice associations are types of HMOs.

Limiting charge – the limit on the amount a non-participating doctor can charge on a non-assigned claim. The limiting charge is no more than 115 percent of the fee schedule.

Mass immunizer – provider who chooses to enroll in Medicare with this identifier which demands the provider meet certain criteria and follow certain procedures when immunizing Medicare beneficiaries.

Medicare Summary Notices (MSNs) – the statement sent to the beneficiary explaining how the claim was processed and what payment amount is being made, what applied to the deductible, what services were denied and why, etc.

Medically necessary – Services or supplies that:

- Are proper and needed for the diagnosis or treatment of a medical condition;
- Are provided for the diagnosis, direct care, and treatment of a medical condition;
- Meet the standards of good medical practice in the medical community of the local area; and
- Are not mainly for the convenience for the patient or doctor

Non-assigned claim – a claim which directs payment to the beneficiary.

Non-government entities – entities that do not charge patients who are unable to pay or reduce their charges for patients of limited means, yet expect to be paid if the patient has

health insurance coverage for the services provided, may bill Medicare and expect payment.

Non-participating physician/suppliers – a physician practice/supplier that has not elected to become a Medicare participating physician/supplier, i.e., one that has retained the right to accept assignment on a case-by-case basis (compare to participating physician.)

Participating physician/supplier – a physician practice/supplier that has elected to provide all Medicare Part B services on an assigned basis for a specified period of time.

Primary care physician – A physician who is trained to provide basic care. This includes being the first one to check on health problems and coordinating preventive health care with other doctors, specialists, and therapists.

Railroad Retirement Board (RRB) – an independent agency in the executive branch of the federal government. The RRB's primary function is to administer comprehensive retirement, survivor and unemployment, and sickness programs for the nation's railroad workers and their families under the Railroad Retirement & Railroad Unemployment Insurance Acts. In connection with the retirement program, the RRB has administration responsibilities under the Social Security Act for certain benefit payments for railroad workers' Medicare coverage.

Remittance Notice (RN) – the statement sent to the provider explaining how the claim was processed and what payment amount is being made, what applied to the deductible, what services were denied and why, etc.

Roster billing – (also referred to as simplified roster billing) a process developed by CMS which enables entities that accept assignment who administer the flu and/or PPV vaccine to multiple beneficiaries to bill Medicare for payment using a modified CMS 1450 or CMS 1500 claim form.

Unique Physician Identification Number (UPIN) – a number used to identify a physician in the Medicare program.